

IN RE: DIET DRUGS (PHENTERMINE/
FENFLURAMINE/DEXFENFLURAMINE)
PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO:

v.

2:16 MD 1203

8594

February 2, 2011

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See

(continued...)

To seek Matrix Benefits, a claimant must submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In or around September, 2004, claimant submitted a supplemental Part II of the Green Form⁴ to the Trust signed by his attesting physician, Robert E. Fowles, M.D., F.A.C.C. Based on an echocardiogram dated April 20, 1999, Dr. Fowles attested in Part II of Mr. Farr's supplemental Green Form that claimant had a stroke due to (a) bacterial endocarditis contracted after the use

3. (...continued)

Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

4. The Show Cause Record contains multiple Green Forms, including a Green Form seeking Level V Matrix Benefits. In the submissions supporting his supplemental claim, however, claimant asserts that he is entitled to either Level III or Level IV Matrix Benefits.

of Pondimin® and/or Redux™, (b) chronic atrial fibrillation with left atrial enlargement as defined in the Green Form, or (c) valvular repair and/or replacement surgery that resulted in a permanent condition that meets the criteria for AHA Stroke Outcome Classification System Functional Level II (determined six months or later after the event)⁵ and mitral valve prolapse.⁶ Based on such findings, claimant would be entitled to Matrix B-1, Level IV benefits in the amount of \$216,940.⁷

In the report of claimant's April 20, 1999 echocardiogram, Dr. Fowles stated that claimant had "[b]ileaflet mitral prolapse, especially the posterior" Claimant also submitted a report for a June 14, 2000 echocardiogram. In this report, Dr. Fowles stated that "[t]he mitral valve demonstrated severe posterior leaflet prolapse" Under the Settlement Agreement, mitral valve prolapse is defined as a condition where:

5. Dr. Fowles also attested that claimant underwent surgery to repair or replace the aortic and/or mitral valve(s) after use of Pondimin® and/or Redux™ and that Mr. Farr suffered from moderate mitral regurgitation, a reduced ejection fraction in the range of 50% to 60%, and New York Heart Association Functional Class I symptoms. These conditions, however, are not at issue in this claim.

6. Under the Settlement Agreement, the presence of mitral valve prolapse requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)ii)b).

7. Under the Settlement Agreement, a claimant is entitled to Level IV benefits if he or she suffers a stroke caused by aortic and/or mitral valve surgery when the stroke has produced a permanent condition that meets the criteria of AHA Stroke Outcome Classification Functional Levels II or III determined six months after the event. See Settlement Agreement § IV.B.2.c.(4)(e).

(a) the echocardiogram video tape or disk includes the parasternal long axis view and
(b) that echocardiographic view shows displacement of one or both mitral leaflets >2mm above the atrial-ventricular border during systole, and >5mm leaflet thickening during diastole, as determined by a Board-Certified Cardiologist.

Settlement Agreement § I.39.

In addition, Dr. Fowles attested in the Green Form that claimant did not suffer from chordae tendineae rupture. In the Operative Report of claimant's July 28, 2000 mitral valve replacement, however, the surgeon, Kent W. Jones, M.D., observed that "all of the chordae were markedly elongated as well. All of the chordae on the medial scallop of the posterior leaflet had ruptured making the leaflet flail. To my surprise the chordae on the medial scallop of the anterior leaflet had also ruptured."⁸ As the Trust does not contest Mr. Farr's entitlement to Level IV benefits, the only issue before us is whether claimant is entitled to payment on Matrix A-1 or Matrix B-1.⁹

8. Like mitral valve prolapse, under the Settlement Agreement, the presence of chordae tendineae rupture requires the payment of reduced Matrix Benefits. See id. § IV.B.2.d.(2)(c)ii)c).

9. After an extensive dispute with the Trust, Mr. Farr previously was paid Matrix A-1, Level II benefits in the amount of \$473,032. Mr. Farr subsequently submitted this supplemental claim for Matrix A-1, Level IV benefits. If Mr. Farr's supplemental claim for Level IV benefits is payable only on Matrix B-1, Mr. Farr will not receive any additional payment because the amount to which he would be entitled for his Matrix B-1, Level IV claim is less than the amount he already received for his Matrix A-1, Level II claim. See Settlement Agreement § IV.C.3.

In February, 2006, the Trust forwarded the claim for review by Keith B. Churchwell, M.D., F.A.C.C., one of its auditing cardiologists.¹⁰ In audit, Dr. Churchwell concluded that there was no reasonable medical basis for the attesting physician's finding that claimant did not have chordae tendineae rupture.¹¹ In support of this conclusion, Dr. Churchill stated that "[t]he surgical operative note states clearly that at the time of clinical evaluation of the mitral valve there were multiple ruptured chordae identified."

Based on Dr. Churchwell's finding that claimant had chordae tendineae rupture, and the attesting physician's representation that claimant had mitral valve prolapse, the Trust issued a post-audit determination that Mr. Farr was not entitled to supplemental Matrix Benefits because he was only entitled to Matrix B-1, Level IV benefits. Pursuant to the Rules for the

10. Pursuant to Pretrial Order ("PTO") No. 3882 (Aug. 26, 2004), all Level III, Level IV, and Level V Matrix claims were subject to the Parallel Processing Procedures ("PPP"). As Wyeth did not agree that Mr. Farr had a Matrix A-1, Level IV claim, the Trust audited Mr. Farr's claim pursuant to the PPP.

11. Although Dr. Churchwell originally indicated there was a reasonable medical basis for the attesting physician's finding as to chordae tendineae rupture, in a subsequent declaration, Dr. Churchwell "corrected" his initial attestation to reflect that, after reviewing the July 28, 2000 Operative Report and Surgical Pathology Report, there was no reasonable medical basis for the attesting physician's finding that claimant did not suffer from chordae tendineae rupture.

Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.¹²

In contest, claimant incorporated the arguments he made in an Omnibus Motion Regarding Claim of Richard Farr for Matrix A Benefits and Discovery of Fraudulent Tampering of Audit Results ("Omnibus Motion"), which he filed at the same time he submitted his contest materials. In the Omnibus Motion, Mr. Farr asserted that he is entitled to Matrix A-1, Level IV Benefits because: (1) the Trust, by advising him that he could seek additional Matrix Benefits, purportedly entered into a contract with Mr. Farr, thereby obligating the Trust to pay all of his supplemental benefits on Matrix A-1; and (2) the Trust should be precluded from litigating any reduction factors under principles of collateral estoppel. Alternatively, Mr. Farr asserted that he should be paid Matrix A-1, Level III benefits because his initial claim for Matrix Benefits purportedly "passed audit." In addition, Mr. Farr, relying on a letter from his attesting physician, argued that his injuries were caused by his ingestion of Diet Drugs. Finally, Mr. Farr seeks to take discovery with respect to alleged "tampering with the audit process" by the Trust.

12. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Mr. Farr's claim.

The Trust then issued a final post-audit determination, again determining that Mr. Farr was entitled only to Matrix B-1, Level IV benefits. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Mr. Farr's claim should be paid. On December 28, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6812 (Dec. 28, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on May 4, 2007. The Show Cause Record is now before the court for final determination. See Audit Rule 35.

There are two issues presented for resolution of this claim. First, we must determine whether Mr. Farr correctly argues that the Trust is prohibited, either by contract or the doctrine of collateral estoppel, from reducing Mr. Farr's supplemental claim for Matrix Benefits based on the presence of chordae tendineae rupture or mitral valve prolapse. Second, if we conclude that the Trust may reduce Mr. Farr's supplemental claim for benefits to Matrix B-1, we must determine whether claimant has met his burden in proving that there is a reasonable

medical basis supporting his claim for Matrix A-1, Level IV benefits. See id. Rule 24. Ultimately, if we conclude that there is no reasonable medical basis for the claim, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the claim, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

I.

After reviewing Mr. Farr's Omnibus Motion and the Trust's Memorandum of Law in Response, we find that the Trust is not required to pay all supplemental claims submitted by Mr. Farr for Matrix Benefits on Matrix A-1. As an initial matter, we reject Mr. Farr's argument that the August 9, 2001 letter from the Trust creates an obligation to pay Mr. Farr's supplemental benefits on Matrix A-1. Even if the letter created a binding contract between the Trust and Mr. Farr, a question on which we need not pass, the letter is clear and unambiguous; it states: "I also wish to remind you that if your condition worsens or progresses in the future you will be eligible to apply for additional compensation beyond the A II level." (Emphasis added.) When the language of a contract is clear and unambiguous, we must apply the contract as written. See Bohler-Uddeholm Am., Inc. v. Ellwood Grp., Inc., 247 F.3d 79, 92-93 (3d Cir. 2001). The language in the August 9, 2001 letter

merely advises Mr. Farr that, under the Settlement Agreement, a class member who received Matrix Benefits may submit a supplemental claim for additional benefits. We must apply the contract as written. Accordingly, at best, Mr. Farr had the right to apply for supplemental Matrix Benefits.

We also disagree with claimant that the doctrine of collateral estoppel precludes the Trust from determining that Mr. Farr is only entitled to benefits on Matrix B-1. The doctrine of collateral estoppel applies only "[w]hen an issue of fact or law is actually litigated and determined by a valid and final judgment, and the determination is essential to the judgment." Nat'l R.R. Passenger Corp. v. Pa. Pub. Util. Comm'n, 288 F.3d 519, 525 (3d Cir. 2002) (quoting Restatement (Second) of Judgments § 27 (1980)). Here, the doctrine of collateral estoppel is not implicated because the parties did not litigate Mr. Farr's alleged entitlement to Matrix A-1 benefits and no court entered a final judgment upon which such a determination of his alleged entitlement was essential.¹³ Accordingly, we will deny Mr. Farr's Omnibus Motion.¹⁴

13. For this reason as well, and because the audit and show cause processes approved by this court provide claimant with notice and an opportunity to present evidence in support of his claim, we reject claimant's argument that he has been deprived of due process.

14. We also will deny Mr. Farr's request for a hearing on his Omnibus Motion because it can be resolved as a matter of law.

II.

As we have concluded that the Trust may reduce Mr. Farr's supplemental claim for Matrix Benefits to Matrix B-1, we next must determine whether he has met his burden in proving that there is a reasonable medical basis for his claim for Matrix A-1, Level IV benefits. After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, Mr. Farr concedes the existence of mitral valve prolapse, a reduction factor. Thus, consistent with the requirements of the Settlement Agreement, it is not unfair for Mr. Farr's claim to be reduced to the B Matrix. This is particularly true given that the Show Cause Record reflects that reduction factors existed at the time of claimant's initial claim, yet Mr. Farr received Matrix A-1 benefits based on his initial claim. As we previously have stated, "[s]imply because an undeserving claim has slipped through the cracks so far is no reason for this court to put its imprimatur on a procedure which may allow it to be paid." PTO No. 5625 at 6-7 (Aug. 24, 2005). In this same vein, even if the Trust erroneously agreed to pay Matrix A-1 benefits based on the initial claim, we will not allow the explicit provisions of the Settlement Agreement to be ignored where an undisputed reduction factor exists.

The Settlement Agreement specifically provides that a claimant will receive reduced Matrix Benefits if he or she is diagnosed with specific medical conditions, which include mitral valve prolapse and chordae tendineae rupture. See Settlement

Agreement §§ IV.B.2.d.(2)(c)ii)b)-c). In the present case, Mr. Farr's attesting physician represented in Part II of claimant's Green Form that he had mitral valve prolapse as defined in the Settlement Agreement. Equally significant, in his show cause submission, claimant stated that "[he] does not dispute the existence of a reduction factor." The Settlement Agreement, therefore, requires that Mr. Farr's claim be reduced to Matrix B-1.

To avoid application of the reduction factor of mitral valve prolapse, claimant relies on a letter from his attesting physician, wherein Dr. Fowles asserted that Mr. Farr's ingestion of Diet Drugs, not mitral valve prolapse, was the cause of his injuries. Causation, however, is not at issue in resolving Mr. Farr's claim. Rather, claimant is required to show that he meets the objective criteria set forth in the Settlement Agreement. As we previously concluded:

Class members do not have to demonstrate that their injuries were caused by ingestion of Pondimin and Redux in order to recover Matrix Compensation Benefits. Rather, the Matrices represent an objective system of compensation whereby claimants need only prove that they meet objective criteria to determine which matrix is applicable, which matrix level they qualify for and the age at which that qualification occurred....

PTO No. 1415 at 51 (Aug. 28, 2000). In addition, we noted:

... [I]ndividual issues relating to causation, injury and damage also disappear because the settlement's objective criteria provide for an objective scheme of compensation.

Id. at 97. If claimants are not required to demonstrate causation, the converse also is true; namely, in applying the terms of the Settlement Agreement, the Trust does not need to establish that a reduction factor caused the regurgitation or other medical condition at issue. The Settlement Agreement clearly and unequivocally requires a claim to be reduced to Matrix B-1 if mitral valve prolapse is present. We must apply the Settlement Agreement as written. Accordingly, the attesting physician's opinion that claimant's mitral valve prolapse was not the cause of his VHD and valve replacement surgery is irrelevant.

Finally, we reject claimant's argument that he is entitled to discovery with respect to the Trust's purported misconduct in auditing his claims for Matrix Benefits. While claimant discusses at length the audit history of both his initial and supplemental claims,¹⁵ he ignores the dispositive fact that, in his supplemental claim, the attesting physician specifically attested to the existence of mitral valve prolapse, a reduction factor. Reducing a claim to Matrix B-1 clearly is

15. In the audits of both Mr. Farr's initial claim and supplemental claim, the auditing cardiologists initially concluded that there was a reasonable medical basis for the attesting physician's findings that claimant did not suffer from chordae tendineae rupture. Given our disposition with respect to the existence of mitral valve prolapse, however, we need not address the potential applicability of the reduction factor of chordae tendineae rupture.

appropriate where the presence of a reduction factor is admitted by both claimant and his attesting physician.¹⁶

For the foregoing reasons, we conclude that claimant has not met his burden of proving that there is a reasonable medical basis for his claim for Matrix A-1, Level IV benefits. Therefore, we will affirm the Trust's denial of Mr. Farr's claim for Matrix A-1 benefits and the related derivative claim submitted by his child.

16. For all of these reasons as well, we also reject Mr. Farr's alternative argument that he is entitled to Matrix A-1, Level III benefits based on his Green Form submitted in October, 2000.